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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,669	11/27/2001	Ann-Kristin Karlsson	06275-160002	1605

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/993,669	KARLSSON ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65,66,68-144 and 146-157* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65,66,68-144 and 146-157* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 94-100 have been amended. Claims 148-157 are newly added. Claims 65, 66, 68-144 and 146-157 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration filed on November 1, 2007 under 37 CFR 1.131 is sufficient to overcome the Harris et al (US 6,187,765) reference.

With respect to the rejections of record that did not include Harris, Applicant cites McAffer et al (US 6,863,865) as a description of the state of the art with respect to the sterilization of budesonide. McAffer asserts that it allows sterilization of a budesonide suspension "for which this was previously believed not possible." It is noted that the basis of McAffer's statement is the report in WO 99/25359 (Astra). This publication is the basis for the instant application. Therefore, Applicant is essentially citing their own specification as an independent description of the state of the art. This is not persuasive. However, it is also noted that McAffer discloses the autoclave sterilization of a suspension of budesonide at Table 4. It is noted that the sterilized product does not meet the purity requirements of the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 65, 66, 69-117, 121-123, 127-132, 136-138, 142-144 and 146-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Day et al (Am. J. Rhinol., 1997) with Monthly Prescribing Reference (MPR) – http://formulary.prescribingreference.com/monograph/sho/d/3269 (accessed February 29, 2008) and Jonsson et al (Drug Metab. Dep., 1995) to support inherency.

Day discloses the treatment of allergic rhinitis with budesonide comprised in the commercial product, Rhinocort Aqua. See abstract.

Jonsson teaches that the 22R epimer has three times the anti-inflammatory potency as the 22S epimer.

MPR describes Rhinocort Aqua as a micronized suspension of budesonide. The product is not further described with respect to the particular components of the suspension, pH, particle sizes, etc. It is also silent regarding sterility. However, given that the product is a commercial pharmaceutical product, it is reasonable to expect that it is sold as a sterile product. Furthermore, given that is disclosed as being used for the same method as Applicant, it is reasonable to expect that the more potent epimer is used, and it contains the instantly claimed suspension components, etc. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 65, 66, 68-93, 115-117, 124-126 and 146-157 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al (Respir. Med., 1994) with Crompton (Lung, 1990) and Jonsson et al (Drug Metab. Dep., 1995) to support inherency.

Jones teaches the administration of budesonide using the product Pulmicort Turbohaler for the treatment of asthma. See abstract.

Crompton teaches that Turbohaler devices dispense inhaled corticosteroids in the form of a micronized powder. See abstract and paragraph bridging pp 660-661.

Jonsson teaches that the 22R epimer has three times the anti-inflammatory potency as the 22S epimer.

The product is not further described with respect to particle sizes, etc. It is also silent regarding sterility. However, given that the product is a commercial pharmaceutical product, it is reasonable to expect that it is sold as a sterile product. Furthermore, given that is disclosed as being used for the same method as Applicant, it is reasonable to expect that the more potent epimer is used, and it contains the instantly claimed suspension components, etc. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

Claims 118-120 and 133-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (Am. J. Rhinol., 1997) with Monthly Prescribing Reference (MPR) –

http://formulary.prescribingreference.com/monograph/sho/d/3269 (accessed February 29, 2008) as applied to claims 65, 66, 69-117, 121-123, 127-132, 136-138, 142-144 and 146-157 above, and further in view of Morice et al (Clin. Pharmacol. Ther., 1996).

Day and MPR teach as set forth above. The references do not teach the treatment of COPD.

Morice teaches the administration of nebulized budesonide for the treatment of COPD. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the budesonide product discussed above for the treatment of COPD with a reasonable expectation of success because Morice had taught that budesonide has this utility.

Claims 139-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (Am. J. Rhinol., 1997) with Monthly Prescribing Reference (MPR) – http://formulary.prescribingreference.com/ monograph/sho/d/3269 (accessed February 29, 2008) as applied to claims 65, 66, 69-117, 121-123, 127-132, 136-138, 142-144 and 146-157 above, and further in view of Jones et al (Respir. Med., 1994).

Day and MPR teach as set forth above. The references do not teach the treatment of asthma.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer the budesonide product discussed above for the treatment of

asthma with a reasonable expectation of success because Jones had taught that budesonide has this utility.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday from 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

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/Leigh C. Maier/
Primary Examiner, Art Unit 1623
February 29, 2008